

REMARKS

Claims 27-29 and 32-35 are pending. Claims 1-26, 30, 31 and 36-42 have been canceled as being directed to non-elected subject matter of the Restriction Requirement.

Claims 1-26, 30, 31 and 36-42 have been canceled in accordance with 37 C.F.R. § 1.144. As such, this reply to the Office Action is complete.

CLAIM TO PRIORITY FROM U.S. PROVISIONAL APPLICATION 60/393,680

The Office Action has asserted that the benefit of Priority Date granted to the above-identified Non-Provisional U.S. Application is the filing date of PCT/US03/20984, *i.e.*, July 2, 2003. The Office Action has undertaken a side by side comparison of U.S. Provisional Application Serial Number 60/393,680, filed July 2, 2002, and the present application based upon PCT/US03/2094, filed July 2, 2003. As a result of that comparison, the Office Action states:

[S]ome of the features taken as example (e.g., structures) that are absent in the provisional application (i.e., US Provisional Application Number 60/393,080 filed 02 July 2002), but are present in the Claims as well as the specification of the instant Non-Provisional US Application Number 10/519,731 filed 05 July 2005. Accordingly, in view of the fact that the disclosure of the instant Non-Provisional US Application Number 10/519,731 is similar to the disclosure of PCT/US03/20984; the benefit of Priority date granted to the instant Non-Provisional US Application Number 10/519,731 is the filing date of 02 July 2003, with is the filing date of PCT/US03/20984.

Applicants respectfully disagree.

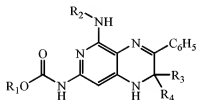
The present Office Action states “[a] separate analysis is required to grant benefit of priority date. Said analysis requires complete review and side-by-side comparison of the Claims and specification recited in said Provisional application filed 02 July 2002 *vis-à-vis* claims and specification of the instant National stage Non-Provisional application with a filing date of 05 July 2005.”

Provisional applications are filed under 35 U.S.C. § 111(b) which does not require that a Provisional application contain appended claims but that the description contained in the specification satisfies 35 U.S.C. § 112, first paragraph, and any drawings comply with the requirements under 37 C.F.R. § 1.81(a). As such, any comparison between the single claim of

Provisional application serial no. 60/393,080 and the claims of the non-Provisional application PCT/US03/20984 is improper for determining the priority date of the present application. Because the single claim recited in the Provisional application does not contain a generic structure is not a proper reason for denying the present application the priority date of Provisional application 60/393,080.

The Office Action when comparing the Utility application with the Provisional application states “[t]he Specification [of the Provisional application] including Claims totals 43 pages” whereas for the PCT application “[t]he Specification excluding Claims page, totals 92 Pages.” The test for whether a Provisional application satisfies the requirements necessary to be a priority document is not related to the number of pages or the difference in the number of pages between the Provisional application and the Utility application. Instead, the Provisional application must satisfy the written description and best mode requirements under 35 U.S.C. § 112, first paragraph (MPEP § 601.01).

Support for Claim 27 can be found throughout the specification. For example, Table 4 on page 43 represents an overview of the structure activity relationship disclosed at page 11, line 17 to page 15, line 2. Referring to the formula at Table 4, this disclosure teaches the contribution of each section of the various pharmacophores contained within the generic formula:



The specification teaches inhibition of *M. tuberculosis* FtsZ by compounds within this generic formula. The mere fact this generic formula is not as broad as that found in Claim 27 does not provide a basis for denying the Applicants right to claim priority to the Provisional application. Once an invention is reduced to practice and an application filed, Applicants are not barred from further development of their invention through use and/or experimentation. All that is necessary is to satisfy the written description, enablement, and best mode requirements. The number of pages in a provisional application does not relate in any way to the question as to whether the requirements of 35 U.S.C. § 112, first paragraph, have been satisfied.

Applicants respectfully request reconsideration and the benefit of priority of the present application to U.S. Provisional Application Serial Number 60/393,680, filed July 2, 2002.

REJECTION UNDER 35 U.S.C. § 103(a)

The Office Action has rejected Claims 27-29 and 32-35 under 35 U.S.C. § 103(a), as allegedly being anticipated by White *et al.*, “Slow Polymerization of *Mycobacterium tuberculosis* FtsZ,” *Journal of Bacteriology*, Vol. 182, pp. 4028-4034 (200) (hereinafter “White 1”) in view of White *et al.*, “2-Alkoxy carbonylaminopyridines: inhibitors of *Mycobacterium tuberculosis* FtsZ,” *Journal of Antimicrobial Chemotherapy*, Vol. 50 pp. 111-114 (2002) (hereinafter “White 2”) and in further view of U.S. 6,319, 958 B1 (hereinafter “Johnson”). Applicants respectfully disagree.

In order for a reference to be considered as prior art under 35 U.S.C. § 103(a), it must also qualify as a reference under one or more of the provisions of 35 U.S.C. § 102. Specifically, a reference under 35 U.S.C. § 102(a) must disclose:

[that which was] known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

Applicants include herewith a Katz-type Declaration, as Exhibit A. Specifically, the Declaration by co-author and co-inventor Dr. Robert C. Reynolds states:

Co-authors, Larry J. Ross, and Laine E. Seitz, of the White *et al.* article did not participate in the conception and reduction to practice of the subject matter of Claims 27-29 and 32-35 of the above-identified application. Therefore, Larry J. Ross, and Laine E. Seitz were included as a co-authors in the White *et al.* article for their contribution, but were not involved in the conception of the method recited in Claims 27-29 and 32-35

Therefore, Larry J. Ross, and Laine E. Seitz are not co-inventors as to the presently claimed invention. Thus, the White 2 reference does not disclose the claimed invention “by others” and therefore does not qualify as a reference under 35 U.S.C. § 102(a) and should be removed as a reference under 35 U.S.C. § 103(a).

Applicants now wish to address this rejection as it relates to the remaining references. In the previous Office Action dated September 26, 2008, the Office set forth the reasons for rejecting the present claims. The reasons for rejecting the claims were not reiterated in the present Office Action. The previous Office Action stated “White *et al.* [White 1] teach [a] method [for inhibiting] polymerization of *Mycobacterium tuberculosis* FtsZ by a tubulin

polymerization inhibitor, (*i.e.*, SRI 7614) having a structure similar to that of an 2-Alkoxyacetylaminopyridine (Abstract, lines 7-9). White et al, however, are silent about the polymerization of *Mycobacterium tuberculosis* FtsZ by [8-(4-diethylamino 1-methylbutylamino)-2,3-diphenylpyrido[2,3-b]pyrazin-6-yl]carbamic acid ethyl ester (*i.e.*, SRI-3072), or putting the bacterial cell and the FtsZ inhibitor in contact with a permeability enhancer, *e.g.*, polymyxin B.”

As it relates to Johnson, the Office Action states “despite being silent regarding the specific microorganism, Johnson *et al.* teach enhancing the uptake of an exogenous material in a Gram positive bacterial cell by putting said bacterial cell in contact with polymeric B.” Johnson discloses at col. 3, lines 3-11:

The present invention is a method of promoting the enhanced uptake of exogenous antimicrobial compounds including antibiotics, by cell of bacteria and fungi. The method comprises the step of exposing the microorganism to a mixture comprising a sesquiterpenoid and the antimicrobial compound. In a preferred embodiment of the present invention, one would apply a composition comprising an amount of sesquiterpenoid sufficient to increase microorganism permeability combined with an antibiotic.

As it relates to Claim 27, the requirement of having a permeability enhancer present is absent from this claim. As for Claims 32 to 35, the artisan would not be motivated to modify the disclosure of Johnson in a manner that would remove the sesquiterpenoid permeability enhancer and to substitute for it a permeability enhancer as recited in Claim 33, *i.e.*, polymyxin B, surface active agents, defensins, other membrane active peptides and chelating agents, or, alternatively, to link an antimicrobial agent to any permeability enhancer *per se*. Modifying Johnson to remove the sesquiterpenoid permeability enhancer would render the method disclosed in Johnson inoperable.

The Office Action asserts that “adjustments of particular conventional working conditions (*e.g.*, microbial organism, ceqialent [equivalent?] compounds that inhibit certain physiological aspect in a Gram positive bacterium/method steps *etc.*) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter that is well within the purview of the skilled artisan.” Indeed, as also stated in the Office Action “White et al...are silent about the polymerization of *Mycobacterium tuberculosis* FtsZ” and Johnson requires a particular sesquiterpenoid permeability enhancer while “being silent regarding the specific microorganism” *i.e.*, *M. tuberculosis*. As such, the Office Action suggests it would be routine

for the artisan to select *M. tuberculosis* as a target in view of the thousands of known organisms, especially when there is no teaching of *M. tuberculosis* FtsZ polymerization in White, and once having selected *M. tuberculosis*, then decide to target the inhibition of FtsZ polymerization in *M. tuberculosis* with a composition that does not comprise Johnson's required sequiterpenoid permeability enhancer; or, in fact, with a composition that is absent a permeability enhancer *per se* as recited in Claim 27. The combination of White 1 and Johnson do not suggest the method recited in Claims 27-29 and 32-35.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 27-29 and 32-35 under 35 U.S.C. § 103(a).

CONCLUSION

Pursuant to the above Remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

A credit card payment submitted *via* EFS Web in the amount of \$960.00 is enclosed herewith. This fee includes the \$405.00 fee under 37 C.F.R. § 1.17(e) for the Request for Continued Examination (Small Entity) and the \$555.00 fee under 37 C.F.R. § 1.17(a)(3) for the Three-Month Extension of Time (Small Entity). No further fees are believed to be due; however, the Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

BALLARD SPAHR LLP

/ Richard S. Echler /
Richard S. Echler
Registration No. 41,006

Customer Number 23859
(678) 420-9300 Phone
(678) 420-9301 Fax

CERTIFICATE OF ELECTRONIC TRANSMISSION UNDER 37 C.F.R. § 1.8			
I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted via electronic transmission via EFS-Web on the date indicated below.			
Name of Person Signing (Print/Type)	Richard S. Echler		
Signature	/ Richard S. Echler/	Date	October 28, 2009